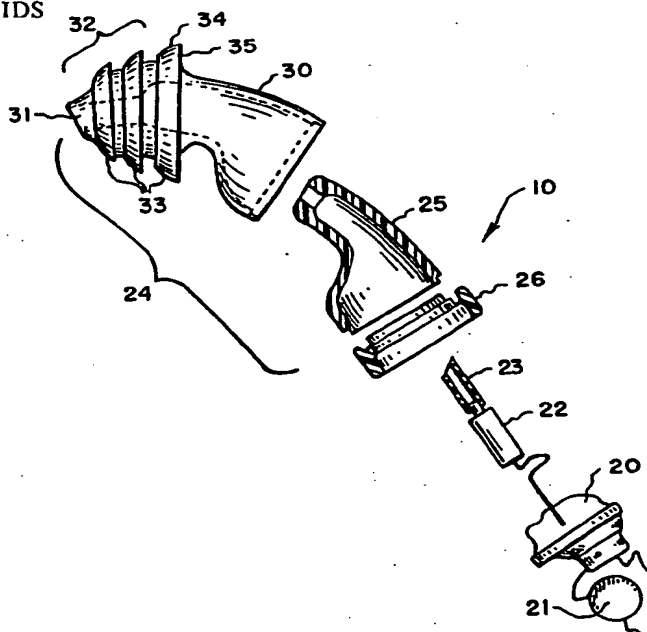


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(21) International Application Number: PCT/US93/04966 (22) International Filing Date: 24 May 1993 (24.05.93) (30) Priority data: 07/888,958 26 May 1992 (26.05.92) US (71) Applicant: BAUSCH & LOMB INCORPORATED [US/US]; Patent Law Department, One Lincoln First Square, P.O. Box 54, Rochester, NY 14601-0054 (US). (72) Inventors: VOROBA, Barry ; 5509 Vine Hill Road, Minnetonkan, MN 55359 (US). WILKINSON, James, P. ; 3661 County Road 90, Independence, MN 55359 (US). ANDERSON, Marlyn ; 3913 Brunswick Avenue, St. Louis Park, MN 55416 (US).		(74) Agents: BIEBER, James, B. et al.; Bausch & Lomb Incorporated, Patent Law Department, One Lincoln First Square, P.O. Box 54, Rochester, NY 14601-0054 (US). (81) Designated States: AT, AU, BB, BG, BR, CA, CH, DE, DK, ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MN, MW, NL, NO, PL, RO, RU, SD, SE, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: SOFT EAR SHELL FOR HEARING AIDS**(57) Abstract**

The invention is a hearing aid earshell assembly for advancing amplified sound deep into a user's ear canal adjacent the eardrum. The earshell assembly includes a core of hollow, rigid construction for containing hearing aid components wherein the core includes an external portion that generally conforms to and extends into a portion of the ear canal. The earshell assembly also includes an earshell or sleeve that encloses the core and further advances amplified sound deeply in the canal and provides an acoustical seal at its distal end in the bony portion of the ear canal to improve the effectiveness of the hearing aid, wherein the earshell is formed of a soft polymer having a Shore A Durometer hardness value of less than 50, preferably less than 10. The earshell is preferably reinforced with a fibrous mesh embedded in the earshell polymer, preferably a mesh formed of silicone elastomer. The preferred polymer of construction of the earshell is a silicone rubber, liquid rubber, polyurethane or combinations thereof.

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SOFT EARSHELL FOR HEARING AIDS

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to hearing aids. More particularly, the invention relates to those hearing aids that include an earmold or earshell assembly that is fitted into a user's ear canal, wherein the earshell typically contains miniaturized components for delivering amplified sound adjacent the ear drum.

Description of the Prior Art

Hearing aids, whether a behind-the-ear (BTE) or in-the-ear (ITE) design, include an earmold or earshell assembly that extends at least nominally into the ear canal to deliver amplified sound. Conventional earmolds are constructed of hard plastic, typically dental acrylics, and fitted by means of an impression of the user's ear, production at a laboratory and perhaps several refittings. Even though these earmolds are produced from individual impressions, the resulting product is a source of many complaints related to fitting and performance. Feedback, in the form of unpleasant squealing, wherein sound delivered from the loudspeaker/receiver leaks back to the microphone, is a common complaint, typically resulting from gaps between earmold surfaces and the inner surfaces of the ear. Where the gaps are minimal and a good seal established, the user often complains of his/her own voice sounding hollow and unnatural booming.

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Traditionally, attempts to deal with this hollow sound or "occlusion" effect have focused upon providing venting of the earmold to reduce excess sound pressure in the ear canal. This solution, of course, tends to cause excessive feedback requiring careful and often unsuccessful balancing of the occlusion effect with feedback.

Additional difficulties arise from the hardness characteristics of the materials of construction of the earmold, which are particularly evident when the earmold is tightly fitted. The earmold may simply cause a great deal of discomfort to the wearer, as insertion in the ear requires the ear canal surfaces to conform to hard, non-yielding earmold surfaces. Retention of the device in the ear also becomes a problem for many users where a strong jaw action tends to cause slippage or even ejection of the device from its position in the ear.

Many of the above-described difficulties were addressed by Voroba et al, in U.S. 4,870,688 which describes an in-the-ear canal hearing aid. In ITE hearing aids, all of the electronics are contained within a hollow, rigid core or shell body that includes an enlarged portion that fits into the concha of the ear and a portion that extends into the ear canal for advancing the amplified sound adjacent the eardrum. The overall design of the core is to substantially conform to the anatomy of the ear and the ear canal. The core element is fitted with a soft, resilient sleeve or covering affixed to the exterior of the core body such that the exterior surfaces of the sleeve conform to adjacent ear canal surfaces while further advancing the amplified sound, about $3/8$ to $3/4$ of the depth of the ear canal. Voroba avoids individual

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impressions by varying the shape, size or thickness of the sleeve covering, allowing the patient to select the best, most comfortable fit. The Voroba covering is characterized by a flexible tip that will accommodate the second bend of the ear canal and provide a deep, in-the-ear canal acoustic seal, which is a key element in avoiding the occlusion effect without the necessity of extensive venting which tends to create feedback problems. A key element of the Voroba '688 resilient sleeve is its low hardness or soft materials of construction. Utilizing a soft polymer material permits the desired deep penetration into the ear canal without causing discomfort to the user. The cover generally comprises an enlarged distal end which, in combination with the soft material of construction, provides improved acoustical sealing, deep within the ear canal.

Harada, in U.S. 4,375,016 also describes an ITE hearing aid that includes an earmold comprising a hard, molded case for containing the electronics and a soft, vinyl casing boot or sleeve projecting into the auditory canal. Again, as in Voroba, the intent is to form a tight, acoustical seal with a somewhat bulbous, flexible tip.

While a key element of some flexible polymer sleeves or covers for advancing the amplified sound proximate the eardrum and providing acoustical seals has been low hardness or increased softness of the material of construction, a significant limitation on reducing the hardness of these designs has been a lack of durability. Since the earshell is frequently removed and reinstalled in the ear, it is subject to significant wear and tear. The problem is particularly significant where it is desired, as

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in Voroba '688, to achieve deep ear canal placement of the amplified sound. Thus, it remains a desirable goal to further reduce the hardness of the materials of construction of the sleeve or cover element of the hearing aid and yet maintain its durability.

SUMMARY OF THE INVENTION

It is an object of the invention to provide a hearing aid having components that advance amplified sound deeply into a user's ear canal adjacent the eardrum. The hearing aid of the invention, comprises: a core means of hollow, rigid construction for substantially containing said hearing aid components, said core having an external portion that generally conforms to and extends into a portion of the ear canal; and an earshell means for substantially enclosing said core and further advancing amplified sound deeply into said canal to improve the effectiveness of said aid, wherein said earshell is formed of a soft polymer having a Shore A Durometer hardness value of less than 50.

Preferably, the earshell of the invention comprises a means for reinforcing the strength of the earshell, said reinforcing means bonded to said polymer. The earshell reinforcing means is preferably a fibrous mesh embedded in said earshell polymer, for example, a mesh formed of a polyester fiber such as Dacron®.

The earshell of the invention is shaped and dimensioned such that its tip extends past the first bend in the ear canal, in a generally S-shaped form, and penetrates at least 3/8 to 3/4 or more of the length of the ear canal. The surfaces of said

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earshell are substantially in sound-sealing contact with said ear canal surfaces, particularly within the bony portion of the ear canal, such that occlusion effects are minimized.

The earshell of the invention preferably comprises at its distal end at least one flange element extending therefrom, said flange a hollow disk-like structure fixed to said earshell. The flange is shaped and dimensioned such that upon insertion an ear said flange compresses and enhances sound-sealing contact between said earshell and the ear canal surfaces.

A key element of the earshell of the invention is its materials of construction which preferably comprises a silicone rubber, liquid rubber, a polyurethane or combinations thereof, having a Shore A Durometer hardness value of about 10 to about 50. Preferably, the polymer selected is as soft as possible; having a hardness value of about 10. A preferred polymer is a silicone rubber having a hardness value of about 10-20 which may be further reduced by mixing with a silicone fluid of 50-1000 cs viscosity.

Where the earshell of the invention includes a reinforcing means, the rigid core preferably includes a flexible means, such as corrugations, near the core distal end, to better accommodate an individual's ear canal configuration, thus improving fit and comfort of the earshell assembly.

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BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic, partial sectional elevation of a modular, in-the-ear hearing aid, showing the principle earshell assembly of the invention.

Figure 2 is an isometric view of another preferred embodiment of the earshell assembly of the invention, including a core and earshell sleeve.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention focuses primarily upon providing an earshell assembly that advances delivery of amplified sound deep in the ear canal adjacent the eardrum in a manner that avoids the hollow voice or occlusion effect and minimizes feedback while providing a comfortable fit wherein the earshell assembly is retained in position in the ear even where there is strong user jaw action. The earshell assembly substantially conforms to an individual's irregular, S-shaped ear canal, as described by Voroba et al in U.S. 4,870,688. As described and demonstrated therein, the earshell assembly of the present invention will likewise extend about 3/8 to 3/4 or more of the length of the ear canal in approaching the eardrum.

Referring to Figure 1, an in-the-ear (ITE) hearing aid 10 including the invention, is shown schematically in an elevational partial sectional view. It is to be understood that the invention may be utilized with any hearing aid device wherein it is desired to advance amplified sound to the eardrum. The ITE conventionally comprises an electronic component 20 typically including a

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microphone, an amplifier, attendant volume and on/off controls (not shown in detail). The electronic component also includes a battery 21 here shown in the battery installation or replacement position. The ITE includes a loudspeaker/receiver 22 for delivering amplified sound adjacent the eardrum, the sound discharge of which is provided with a flexible extension tube 23 for further advancing amplified sound adjacent the eardrum.

The electronic components are fitted into an earshell assembly 24 that comprises a rigid hollow core 25 for containing and protecting the electronics from the environment. The core 25 is externally shaped to include a portion for containing most of the electronics that substantially conforms to the concha, transitioning into a portion that fits into the ear canal. A flange 26 is provided, that is fixed to the core 25, into which the electrical component 20 snap locks. A detailed description of an example of suitable core and flange elements is found in U.S. '688.

A key element of the invention is an earshell sleeve or cover 30 for substantially enclosing the core, finally advancing the sound discharge tube 23 of the receiver 22 as near to the eardrum as desired and providing an acoustical seal between the earshell assembly and ear canal surfaces. The earshell 30 is of hollow, thin shell construction having internal dimensions adequate to receive and enclose the core 25. The earshell 30 is provided with at least one aperture 31 for accommodating the receiver tube 26. Other apertures (not shown) are typically provided for venting the earshell assembly. The earshell 30 is preferably bonded to

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the core 25 external surfaces, typically by means of an adhesive.

The earshell 30 is provided with a substantially bulbous tip 32 to insure that an acoustical seal is achieved deep in the ear canal, in the bony portion of the canal. The deep seal is important in substantially reducing the hollow voice or occlusion effect. The seal in itself is, of course, important in reducing and controlling feedback. However, establishing a seal deep in the ear canal substantially eliminates the occlusion effect by means which avoids the conventional solution of venting which typically led to excessive feedback. Venting to equalize canal pressure to atmospheric is still desirable to prevent discomfort and a feeling of fullness that is usually associated with an insertion of an object into the canal. However, it is now possible to reduce and control the venting to just achieve the pressure relief desirable while minimizing acoustical feedback.

Referring again to Figure 1, the earshell 30 of the invention preferably includes a series of flanges 33 extending from the generally bulbous tip portion 32. These flanges 33 at least partially collapse rearwardly as the ITE is inserted into the ear. The flanges further assist and insure a good acoustical seal deep in the ear canal. The flanges also act as a means for retaining the earshell 30 in position within the ear canal, even during strong jaw movement. The softness of the material of construction of the earshell, of course, also aids in retention by absorbing and dampening energy from jaw movement which causes the ear canal to change shape. The flanges are formed of soft polymer

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material, preferably having a Durometer of about 10-20 hardness.

When placed in the ear, the flanges 33 fold into a retentive position. The flanges are preferably spaced apart such that a space or pocket is formed between them which assists in the ability of the earshell 30 to overcome slippage.

The upper rounded surface 34 of each flange facilitates the insertion of the earshell into the ear canal. The angle of attack of the rounded surface may be varied with ear shape and size. The edge and undersurface 35 of the flange is shaped to provide resistive force against withdrawal. The undersurface 35 of the flange is preferably flat or curved inwardly to assist in creating a lock within the ear canal. It will be clear to those skilled in the art that the earshell may be varied in shape and size to conform to the individual's ear canal. However, the materials of construction and flange structure selected are sufficiently soft and resilient to conform to ear canal passages without causing discomfort and yet, are not readily expelled from the ear canal by the user's jaw action.

A key element of the earshell of the invention is its material of construction which is characterized by softness or low hardness expressed in terms of Shore A Durometer hardness value, measured by ASTM Method 2240-81. A Shore A Durometer hardness value in the range of about 10 to about 50 is preferred. Materials having a durometer hardness value of between 10 and 20 are most preferred.

The earshell 30 is preferably made of supersoft, flexible, compressible, resilient, oil resistant, non-toxic, non-allergenic type rubber or

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polymeric material. The earshell is easily produced by injection molding of silicone rubber or liquid rubber in an appropriately shaped mold (not shown).

An example of a low durometer injection material with superior elongation qualities is a silicone rubber, Liquid Rubber LR-15, manufactured by Wacker Silicones Corporation of Adrian, Michigan, having a cured durometer value of about 20. LR-15 is a conventional silicone, formulated primarily for use in injection molding equipment, and comprises a two-component system that cures rapidly, upon heating, to a tough translucent silicone rubber. Curing is initiated by mixing equal parts by weight of LR-15 Part A and Part B, wherein the Part B molecules bond with vinyl groups on the Part A molecules to form crosslinks. The degree of crosslinking and overall length of the molecules determine the hardness and strength of the final product. The soft material of earshell 30 may be made with a greater percentage of LR-15 Part A than Part B (i.e. a 60-40 ratio) leaving a small amount of Part A unreacted and creating a softer composition.

An even softer polymer, having durometer values of around 10 may be utilized by mixing relatively small amounts (about 15 to 20% by weight) of Dow Corning Silicone Fluid 200[®] with Wacker Silicones Corporation's LR-15. Silicone Fluid 200[®] is a medium viscosity linear polydimethylsiloxane polymer with a typical chemical composition of $(CH_3)_3SiO[SiO(CH_2)_2]_nSi(CH_3)_3$, having kinematic viscosities ranging from 50 to 1000 cs. In a preferred embodiment, a supersoft silicone composition is formulated with equal portions of

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LR-15 Part A and LR-15 Part B mixed with a smaller portion of Dow Corning Silicone Fluid 200®, for example, in proportions of approximately 41%-41%-18%.

Those skilled in the art will recognize that other materials may be substituted for LR-15 and Silicone Fluid 200® such that the resulting polymer has similar characteristics such as high compressibility, high damping capacity, superior elongation, high tear strength, and, soft feel and lubricity on the skin. Such other materials are polyurethanes and styrenic thermoplastic elastomers.

As the earshell material is reduced in durometer hardness much below 20, forces exerted upon earshell 30 during removal from the user's ear canal, such as by gripping of hearing aid 10 with the user's fingernails, may cause tearing or excessive wear particularly at the edges adjacent the core. A preferred embodiment of the invention is provided with reinforcing means for improving resistance to stress and strain that cause damage to the earshell.

Referring to Figure 2, a preferred embodiment of an earshell 50 of the invention is shown which includes as a material of construction of the earshell, a reinforcing mesh 51 embedded therein.

The reinforcing mesh 51 is constructed of, for example, a polyester woven mesh such as D-116 fabric, manufactured by Travis Textiles of Hemlock, Michigan. This material is a flexible, high-strength, tear resistant, knitted mesh.

In a preferred embodiment, the reinforcing mesh is formed into a sleeve that substantially conforms to the shape of the earshell. The sleeve is then placed in a mold for injecting or otherwise forming

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with the polymer selected. In making the supporting mesh sleeve, wherein the above noted polyester mesh flat sheet is utilized, the sheeting is first formed into a tube of slightly smaller diameter than the largest diameter of the earshell by gluing with a bead of a medical adhesive. The tube is treated to form fitting capability by applying heat and stress to make the material more elastic. The tube is chopped to length and stretched onto a mandrel having external surfaces that substantially conform to the internal surfaces of the earshell. The tube then is stiffened with starch or the like, followed by molding with the desired polymer such as the above described liquid silicone rubber.

A significant advantage of the earshell of the invention that employs a reinforcing means is that the construction of the core may be modified to significantly improve fit and comfort of the earshell assembly. In general, the core is a unitary, rigid polymer material such that the electronics of the hearing aid are adequately protected. When the core is enclosed in an earshell that is reinforced sufficiently to maintain earshell assembly integrity, the earshell core 52, as shown in Figure 2, may be formed with a flexible element of the core portion that is inserted into the ear canal. Thus, the core 52 includes a flexible corrugated portion 53 which allows improved flexibility at the tip. Such flexibility ensures that the earshell assembly will more easily conform to an individual's ear canal and create less discomforting stress on ear canal surfaces. Of course, alternatives to the core flexible corrugated portion are evident to those skilled in the art, such as simply removing a segment of the ear canal

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extension portion and filling the interior with a flexible polymer to secure positioning of the receiver.

Since many embodiments, modifications and variations of the present invention may be made in view of the above teachings without departing from the spirit of the invention, it will be understood that within the scope of the appended claims, the invention may be practiced. Otherwise then, as specifically described hereinbefore, what is claimed is.

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CLAIMS:

1. A hearing aid having components that are fitted into a user's ear canal to advance amplified sound adjacent the eardrum, comprising:

a core means of hollow, rigid construction for substantially containing said hearing aid components, said core having an external portion that generally conforms to a portion of the ear canal; and

an earshell means for substantially enclosing said core and further advancing amplified sound deeply into said canal to improve the effectiveness of said aid, wherein said earshell is formed of a soft polymer having a Shore A Durometer hardness value of less than 50, and provides an acoustical seal at its distal end adjacent said eardrum.

2. The hearing aid of Claim 1 wherein said hardness value is about 10.

3. The hearing aid of Claim 1 wherein said hardness value is a range of about 10 to about 50.

4. The hearing aid of Claim 1 wherein said earshell means further comprises a means for reinforcing the strength of the earshell, said reinforcing means bonded to said polymer.

5. The hearing aid of Claim 1 wherein said earshell is bonded to said core.

6. The hearing aid of Claim 5 wherein said earshell is bonded to said core external surfaces by means of an adhesive.

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7. The hearing aid of Claim 4 wherein said earshell reinforcing means is a fibrous mesh embedded in said earshell polymer.

8. The hearing aid of Claim 7 wherein said fibrous mesh is formed of polyester fiber.

9. The hearing aid of Claim 1 wherein said earshell is shaped and dimensioned such that its tip extends past the first bend in the ear canal in a generally S-shaped form and penetrates at least $3/8$ to greater than $3/4$ of the length of the ear canal, the surfaces of said earshell being substantially in sound-sealing contact with said ear canal surfaces.

10. The hearing aid of Claim 9 wherein said earshell is shaped and dimensioned such that the earshell tip is in sound sealing contact within the bony portion of the ear canal wherein occlusion effects are minimized.

11. The hearing aid of Claim 1 wherein said earshell comprises at its distal end at least one flange element extending therefrom, said flange a hollow disk-like structure fixed to said earshell, being shaped and dimensioned such that upon insertion of the earshell in the ear, said flange compresses and enhances said sound-sealing contact between said earshell and the ear canal surfaces.

12. The hearing aid of Claim 11 wherein each said earshell flange comprises an angle of attack of between about 20° below the horizontal and about 45° above the horizontal.

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13. The hearing aid of Claim 1 wherein said earshell comprises a silicone rubber, liquid rubber, a polyurethane or combinations thereof, having a Shore A Durometer hardness value of about 10 to about 50.

14. The hearing aid of Claim 13 wherein said earshell comprises a silicone rubber having a cured Shore A Durometer hardness value of about 10-20.

15. The hearing aid of Claim 14 wherein said silicone rubber includes about 15 to 20% by weight of a silicone fluid having a viscosity of about 50-1000 cs.

16. A hearing aid having components that are fitted into a user's ear canal to advance amplified sound adjacent the eardrum, comprising:

a core means of hollow, rigid construction for substantially containing said hearing aid components, said core having an external portion that generally conforms to a portion of the ear canal; and

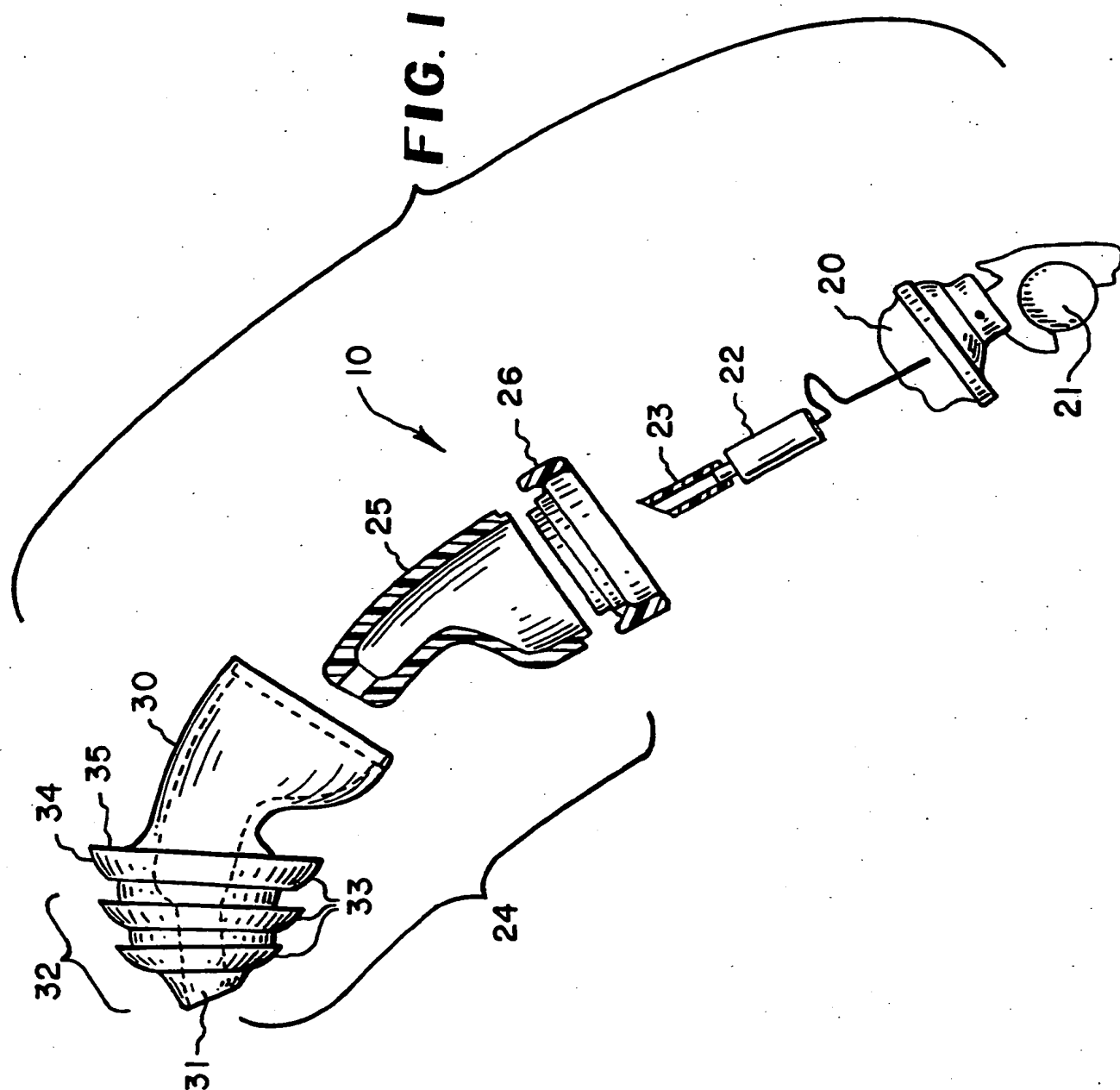
an earshell means for substantially enclosing said core and further advancing amplified sound deeply into said canal to improve the effectiveness of said aid, wherein said earshell is formed of a soft polymer having a Shore A Durometer hardness value of less than 50 and a means for reinforcing the strength of the earshell of said reinforcing means bonded to said polymer, said earshell providing an acoustical seal at its distal end adjacent said eardrum.

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17. The hearing aid of Claim 16 wherein said core portion for extending into the ear canal includes a flexible means for improving accommodation of individual ear canal configuration.

18. The hearing aid of Claim 17 wherein said flexible means is a series of corrugations adjacent the distal end of said core.

19. The hearing aid of Claim 17 wherein said flexible means comprises filling a portion of the interior of said core and positioning the distal end of said core, in the absence of a section of said core adjacent said distal end.



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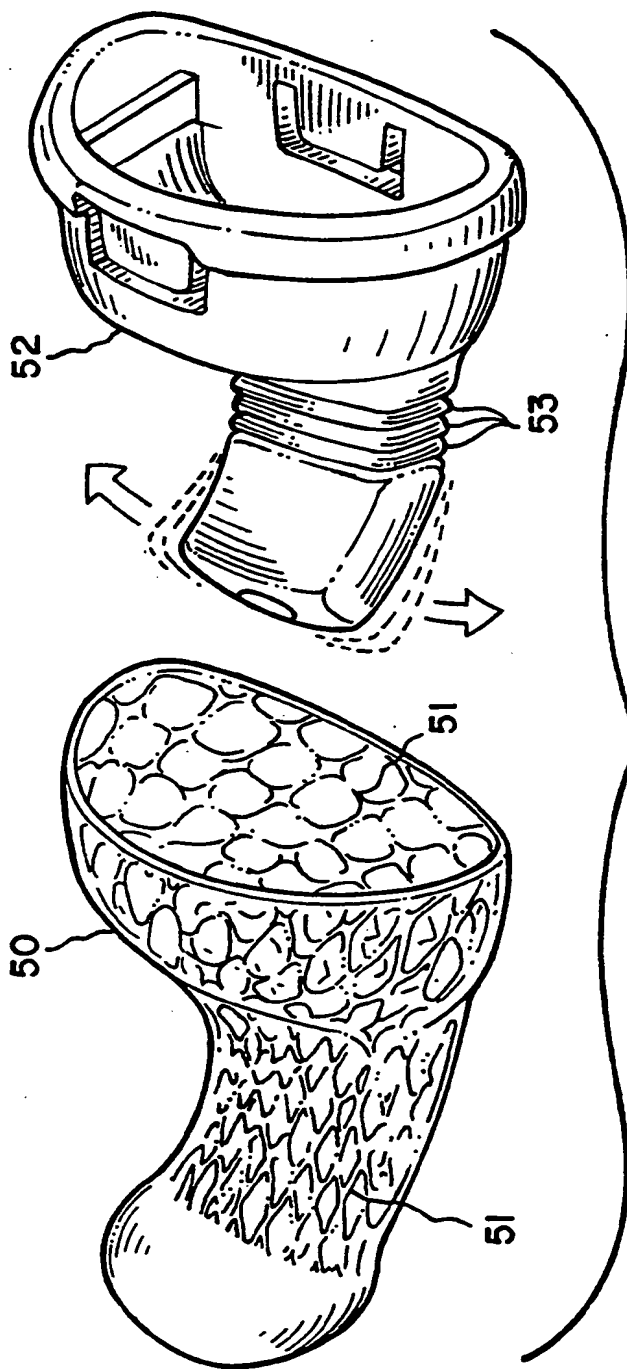


FIG. 2

International Application No.

1. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *

According to International Patent Classification (IPC) or to both National Classification and IPC

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Minimum Documentation Searched ?

Classification System

Classification Symbols

IPC⁵

H 04 R

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched *

III. DOCUMENTS CONSIDERED TO BE RELEVANT*

Category *	Citation of Document, " with indication, where appropriate, of the relevant passages "
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x

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- Special categories of cited documents: 40

- "A" document defining the general state of the art which is not considered to be of particular relevance
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- "P" document published prior to the international filing date but later than the priority date claimed

- T** later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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- Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

- "4" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

23 July 1993

Date of Mailing of this International Search Report

29.09.93

International Searching Authority

EUROPEAN PATENT OFFICE

Signature of Authorized Officer

GRÖSSING e.h.

ANHANG

zum internationalen Recherchen-
bericht über die internationale
Patentanmeldung Nr.

ANNEX

to the International Search
Report to the International Patent
Application No.

ANNEXE

au rapport de recherche inter-
national relatif à la demande de brevet
international n°

PCT/US 93/04966 SAE 75020

In diesem Anhang sind die Mitglieder
der Patentfamilien der in obenge-
nannten internationalen Recherchenbericht
angeführten Patentdokumente angegeben.
Diese Angaben dienen nur zur Unter-
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This Annex lists the patent family
members relating to the patent documents
cited in the above-mentioned inter-
national search report. The Office is
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of information.

La présente annexe indique les
membres de la famille de brevets
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national visée ci-dessus. Les renseigne-
ments fournis sont donnés à titre indica-
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In Recherchenbericht angeführtes Patentdokument Patent document cited in search report Document de brevet cité dans le rapport de recherche	Datum der Veröffentlichung Publication date Date de publication	Mitglied(er) der Patentfamilie Patent family member(s) Membre(s) de la famille de brevets	Datum der Veröffentlichung Publication date Date de publication
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